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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,958	11/18/2003	Ralph C. Craft	9/294	4581

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EXAMINER	
LE, LINH GIANG	

ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
11/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/714,958	CRAFT, RALPH C.	
	Examiner	Art Unit	
	Linh-Giang Le	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to application filed 18 November 2003. Claims 1-15 remain pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shrier (6,317,719).

4. As per claim 1, Shrier teaches an automated data processing method for obtaining clinical data for safety efficacy and adverse event assessments pertaining to a therapy prescribed for the treatment of a malady, said method comprising the steps of:
Receiving at a location remote from a plurality of patients' outcome digital information pertaining to the outcome of therapies performed on said patients (Shrier; Col. 8, lines 36-51);
Digitally processing said digital outcome information to determine an adverse event profile associated with a particular therapy (Shrier; Col. 10, lines 4-15);

Digitally processing said outcome information to determine the efficacy of such therapy in the amelioration or cure of the malady treated (Shrier; Col. 9, lines 38-64); and

Shrier does not expressly teach digitally comparing said adverse event profile with said efficacy to determine a safety profile for said particular therapy. However this is an obvious variant of the Shrier teachings. Shrier teaches a decision tree and comparing different factors to determine proper dosage for a drug (Shrier; Col. 25, line 30-60). Examiner submits that it is an obvious variant of the Shrier teachings of a decision tree to digitally compare the profiles to determine a safety profile. Examiner believes that the step of digitally comparing different types of data to come up with a safety profile is done within a decision tree as taught by Shrier. It would have been obvious to modify the Shrier teachings with the motivation of providing the clinician with ready and convenient access to current, pertinent, and patient-specific drug information and dosing recommendations (Shrier; Col. 1, lines 51-55).

5. As per claim 2, Shrier teaches the method optionally including steps for assessing the pharmaco-economics of said therapy, said steps comprising:

Obtaining digital data pertaining to the cost of said therapy (Shrier; Col. 10, lines 33-44); and

Digitally comparing said efficacy of said therapy with said cost of said therapy (Shrier; Col. 11, lines 30-47).

6. As per claims 3 and 4, Shrier does not expressly teach wherein said therapy is a pharmacointervention or a non-drug associated intervention. Shrier does teach including the therapy type as a factor in the decision tree to determine proper dosage of a drug (Shrier; Col. 25, lines 30-40) but not a specific type of therapy. However this is merely a design change and the type of therapy does not affect the functionality of the method.

7. As per claim 5, Shrier teaches wherein the outcome digital data includes remote disease management data (Shrier; Col. 8, lines 36-50).

8. As per claims 6-8, Shrier does not expressly teach wherein said adverse event profile is transmitted to:

a regulatory agency responsible for monitoring such adverse events;

a regulatory agency responsible for monitoring the effectiveness of therapies;

an insurance company.

However, Examiner takes Official Notice that transmitting patient data to various different parties other than a clinician is old and well known in the art. Shrier teaches transmitting information to a clinician in a clinical setting but one of ordinary skill in the art would recognize that the transmittal of this information is not limited to only a clinician. Sharing this data with various agencies and insurance companies would allow for a maximum number of parties to examine and make use of important patient data.

One would have been motivated to share this data with many parties in order for more parties to assess and evaluate the needs of a patient or group of patients.

9. Claims 9-13, 15 are rejected under 35 USC 103(a) as being unpatentable over Schoonen (6,352,200).

10. As per claim 9, Shoonen teaches a clinical management method in a computer system for the efficient delivery of medications to a patient ordered and keeping track of samples pursuant to an electronic prescription by a caregiver for such patient, said method comprising the steps of:

Determining which of a plurality of dispensaries is optimal for delivery of said medications to said patient based on at least one of: the location of said dispensary, the cost of said medication at each dispensary, or the stock of said medications at each of said dispensaries (Schoonen; Col. 3, lines 50-65); and

Causing said optimal dispensary(ies) to deliver said medication in an amount needed by said patient to complete a therapy round to said patient pursuant to said electronic prescription (Schoonen; Col. 3, lines 50-65).

Schoonen does not expressly teach:

Determining the number of samples provided to said patient of each of said medication(s) prescribed for said patient;

Determining the treatment-time made possible by the number of samples provided to said patient;

Determining the amount of medication(s) needed by said patient to complete a therapy round specified in said electronic prescription;

However, these are obvious variants of the Schoonen teachings. In particular Schoonen does teach a pharmacy computer that checks the prescription request according to a predetermined algorithm. Examiner submits that one of ordinary skill in the art would recognize that the predetermined algorithm could be established to determine the number of samples, treatment time and amount of medication. One of ordinary skill in the art would have been motivated to vary the Schoonen teachings with the motivation of delivering medications efficiently and economically (Schoonen; Col. 2, lines 4-12).

11. As per claims 10-13 Schoonen does not expressly teach wherein at least one of said dispensaries is a: wholesaler of medications; pharmaceutical manufacturer; a pharmacy; or wherein said medications are delivered from to said patient from said dispensary(ies) by mail.

However Examiner respectfully submits that the type of delivery or dispensary is merely a design change and does not affect the functionality of the claims. Examiner does not believe the type of dispensary method affects functionality of the clinical management method described in claim 9.

12. As per claim 15, Schoonen does not expressly teach:

Contacting the patient's prescription insurance carrier in respect to said prescription; and

Calculating any co-pay due on filling of medication needed for a therapy round.

Examiner takes Official Notice that contacting an insurance carrier to determine a co-payment amount is old and well known in the art. One of ordinary skill in the art would recognize that it is common practice for a pharmacy or any prescription distributor to contact an insurance company to determine an exact co-pay amount required by a customer. This is done in order to ensure that a customer pays the correct amount when receiving medication. One would have been motivated to include these steps of contacting a prescription insurance carrier in order for a customer to pay the correct amount upon receiving medication.

13. Claim 14 is rejected under 35 USC 103(a) as being unpatentable over Schoonen (6,352,200) in view of Kobylevsky (6,493,427).

14. As per claim 14, Schoonen does not expressly teach wherein any refills for said medications specified in the electronic prescription are automatically filled and delivered to said patient when said refill is due based on the instructions incorporated in said electronic prescription and/or based on conventional medical practice. However this is well known in the art as evidenced by Kobylevsky. In particular Kobylevsky teaches a prescription refill system that automatically processes pharmacy prescription refills (Kobylevsky; Col. 2, lines 50-53). It would have been obvious to add this feature to the

Schoonen method with the motivation of delivering medications efficiently and econmoically (Schoonen; Col. 2, lines 4-12).

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Linh-Giang Le whose telephone number is 571-272-8207. The examiner can normally be reached on 8 AM - 5PM, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-3600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LLe

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